



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,387	03/26/2003	Maurizio Dalle Carbonare	0259-0411PUS1	6340
2292 7590 03/26/2010 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747				
EXAMINER MAEWALL, SNIGDEHA				
ART UNIT		PAPER NUMBER		
1612				
NOTIFICATION DATE		DELIVERY MODE		
03/26/2010		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary

Application No.

10/019,387

Applicant(s)

DALLE CARBONARE ET AL.

Examiner

Snigdha Maewall

Art Unit

1612

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 November 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-5, 13, 14, 17-19 and 22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-5, 13-14, 17-19 and 22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB06)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ ~~Notes of Informal Patent Application~~
- 6) ☐ Other: _____

DETAILED ACTION

Summary

1. Receipt of Applicant's Arguments/Remarks and Amendments filed on 11/27/09 is acknowledged.

Claims 1-2, 6-12, 15-16 and 20-21 have been canceled in this Application.

Claims 3-4, 14 and 18 have been amended.

Accordingly, claims **3-5, 13-14, 17-19 and 22** are pending in this application.

The rejections made in the previous office action have been withdrawn in view of applicant's amendments to claims.

Applicant's amendments to the claims necessitated the following new rejections.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 3-5, 13-14, 17-18 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3-4, 14 and 18 recite the limitation as 75% benzyl ester of hyaluronic acid, it is

not clear what the rest of the 25% constitutes. appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this

Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claim 4 is rejected under 35 U.S.C. 102(e) as being anticipated by Valentini et al. (US USP 5,939,323).

Valentini teaches a scaffold made up of hyaluronic acid derivative for use of wound healing, tissue repair and tissue reconstruction which comprises a biologically active molecule, abstract. The reference teaches use of HYAFF 11 which is 100% benzylester of hyaluronic acid and 75% benzyl ester of hyaluronic acid such taught in

column 9, lines 39-40. Growth factors were introduced with gel materials (reads on biological or pharmacological compound), see column 10, section e.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 3, 5, 13-14, 17-19 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davidson et al. (Clinical materials (1991, presented in IDS) in view of Valentini et al. (US USP 5,939,323) or vice versa.

Davidson et al. teaches hyaluronate derivatives and their application to wound healing and wound repair with reduced **scarring** (see title and page 171, second column). The reference teaches that hyaluronic acid and its derivatives show as biomaterial in wound healing applications. The hyaluronate treated wounds tended to accumulate collagen more slowly hence showing the capacity of such biomaterials in modifying the scarring process. Such ability shows effect in improving wound healing and repair process (see the first page). The reference teaches formulations can be fabricated into gels and films (reads on non woven as also defined in instant specification (see page 172, 1-5 lines. Experimental procedures have been shown on page 172, on both columns. The results show that ability of hyaluronate and its esterified derivatives stimulate early organization of wound site while moderating the

excessive accumulation of collagen at the stage of scar formation. (See page 174 columns 2, last paragraph).

Davidson et al. do not specifically teach benzyl esters as claimed and utilization of additional biological compound.

Valentini teaches a scaffold made up of hyaluronic acid derivative for use of wound healing, tissue repair and tissue reconstruction which comprises a biologically active molecule, abstract. The reference teaches use of HYAFF 11 which is benzylester of hyaluronic acid and 75% benzyl ester of hyaluronic acid such as taught in column 9, lines 39-40. Growth factors were introduced with gel materials, see column 10 e section.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use 75% benzyl hyaluronic acid esters for the treatment of scarring on the skin by using the composition provided by Valentini et al. motivated by the teachings of Davidson et al. which teaches utilization of hyaluronate esters in wound healing and scarring treatment. Since the instant specification provides experimentation of scarring treatment after creating wound in an animal and then observing the scarring effect, it is evident that wound healing ester of hyaluronic acid of Valentini would treat scarring as per Davidson et al absent evidence to contrary. Regarding claim 19, patent office is not equipped with laboratory to conduct experiments; since the prior art teaches the claimed components and claimed method of treating, one of ordinary would expect similar results. A skilled artisan would have been motivated to use derivatives of hyaluronic acid such as esters of hyaluronic acid in treating the scarring of the skin and treatment of wound with a reasonable expectation of success.

8. Claims 3, 5, 13-14, 17-19 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davidson et al. (Clinical materials (1991, presented in IDS) in view of Dorigatti et al. WO 94/17837, presented in IDS.

The teachings of Davidson and Valentini have been discussed above, the reference of Davidson does not teach benzyl ester specifically and utilization of additional biologically or pharmacologically active compound.

Dorigatti teaches multilayer non woven material comprising a layer in contact with the skin comprising esters of hyaluronic acid; the material can be utilized in medical applications including surgery, abstract. By using non woven tissue production techniques, it is possible to obtain procedures which combine flexibility with the capacity to absorb fluids, see page 1, lines 19-23. The non woven materials can be used in dermatology and treating skin pathologies, see page 3, and lines 22-23. The hyaluronic esters used can be those described in EPA 0216453, USP 4,851,521, 4,965,353 and 5202431, used alone or in mixtures in varying amount percentages, see page 4, lines 27-29. The layer can also comprise collagen, polysaccharides in the form of gel, agar etc. (Reads on biological or pharmacological compound) the example 1 on page 7 discloses HYAFF 11 and non woven layer, the reference also teaches 75% benzyl ester.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use 75% benzyl hyaluronic acid esters as taught by Dorigatti et al. for the treatment of scarring on the skin by using the composition provided by

Dorigatti et al. motivated by the teachings of Davidson et al. which teaches utilization of hyaluronate esters in wound healing and scarring treatment. Dorigatti also teaches utilization of non woven materials for medical applications because it provides fluid absorption, therefore one of ordinary would have been further motivated to utilize non woven material and benzyl ester of hyaluronic acid for wound treatment and ultimate scar reduction. Regarding claim 19, patent office is not equipped with laboratory to conduct experiments; since the prior art teaches the claimed components and claimed method of treating, one of ordinary would expect similar results. A skilled artisan would have been motivated to use derivatives of hyaluronic acid such as esters of hyaluronic acid in treating the scarring of the skin and treatment of wound with a reasonable expectation of success.

Response to Arguments

9. Applicant's arguments with respect to claims 3-5, 13-14, 17-19 and 22 have been considered but are moot in view of the new ground(s) of rejection.

10. DECLARATION SUBMITTED UNDER 37 CFR. § 1.132

Applicant's arguments that the attached are the results of the study conducted and from these results it can be seen that samples D and E according to the present invention exhibited an improvement of about 40% in the wound coverage versus all control samples.

The declaration is insufficient to overcome the rejections made in this office action which are new rejections necessitated by claim amendments.

The prior art discloses the scarring and wound healing effect by benzyl ester of hyaluronic acid. The increase in 40% of wound healing is a matter of degree and not an unexpected result where the prior art as discussed above specifically teaches application of hyaluronic acid benzyl derivatives in treating scars and wounds.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-272-6197. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information

Application/Control Number: 10/019,387

Page 9

Art Unit: 1612

system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Snigdha Maewall/

Examiner, Art Unit 1612

/Gollamudi S Kishore/

Primary Examiner, Art Unit 1612